UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CLARK ALEXANDRE, individually and on behalf of all others similarly situated,

Plaintiff,

-against-

ALCON LABORATORIES, INC.,

Defendant.

OPINION AND ORDER

No. 22-CV-08859

PHILIP M. HALPERN, United States District Judge:

Clark Alexandre ("Plaintiff") brings this putative class action against Alcon Laboratories, Inc. ("Defendant") alleging that the statement "30 Day Supply" on the label of Defendant's "Extra Strength Once Daily Relief" eye drop product is false and misleading. (Doc. 1). Plaintiff amended his complaint on March 15, 2023. (Doc. 11, "AC"). Plaintiff's sole remaining claims for relief are: (i) violations of New York General Business Law ("GBL") §§ 349 and 350; and (ii) breach of Express Warranty.[1]

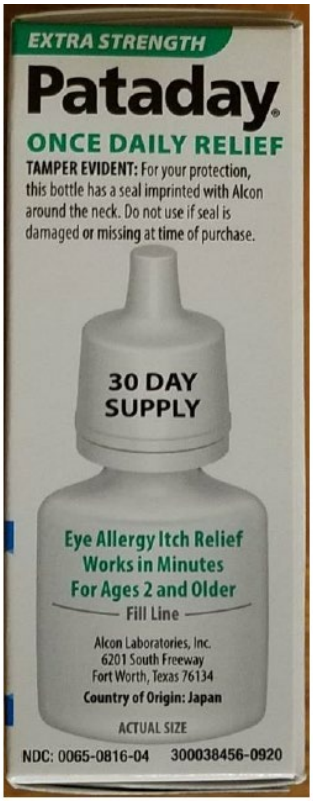
Before the Court is Defendant's motion to dismiss the Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Defendant moved to dismiss on June 26, 2023, in accordance with the briefing schedule set by the Court. (Doc. 20; Doc. 21, "Def. Br."). Plaintiff filed a memorandum of law in opposition (Doc. 23, "Pl. Br."), and the motion was fully submitted upon the filing of Defendant's reply. (Doc. 22, "Reply"). Defendant, with leave of the Court, filed a notice of supplemental authority on January 26, 2024. (Doc. 24; Doc. 25).

For the reasons set forth below, Defendant's motion is DENIED.

[1] On June 7, 2023, on stipulation of the parties, the Court dismissed without prejudice Plaintiff's claims for violation of various State Consumer Fraud Acts and dismissed with prejudice Plaintiff's claims for: (i) breaches of Implied Warranty of Merchantability/Fitness for a Particular Purpose and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, et seq.; (ii) fraud; and (iii) unjust enrichment. (Doc. 19).

BACKGROUND

Defendant manufactures, labels, markets, and sells over-the-counter ("OTC") "Extra Strength Once Daily Relief" under the "Pataday" brand for eye allergy itch relief (the "Product"). (AC ¶ 1). The Product's container includes the phrase "30 Day Supply" and directs consumers to use one drop per day in each eye. (*Id*. ¶ 1-2).



(*Id*.). Plaintiff alleges that use of the Product as directed results in one bottle "last[ing] approximately twenty days instead of the thirty promised on the label." (*Id*. ¶¶ 3, 20).

Plaintiff purchased the Product on multiple occasions during the winter and spring of 2022, among other times, at CVS and Walgreens stores in Rockland County, New York. (*Id*. ¶ 21). Plaintiff used the Product as directed, one drop per day in each eye, to provide eye allergy itch relief and observed over several months that the bottle lasted approximately twenty days. (*Id*. ¶¶ 2-3, 20). Plaintiff thought that he may have purchased irregular batches with less than the amount

indicated, contacted Defendant, and Defendant sent him three replacement bottles. (*Id*. ¶¶ 4-6). The Product continued to last Plaintiff approximately 20 days. (*Id*. ¶¶ 5-6). Plaintiff allegedly relied on "the words, terms[,] coloring, descriptions, layout, placement, packaging, tags, and/or images on the Product, on the labeling, statements, omissions, claims, and instructions, made by Defendant . . . ." (*Id*. ¶ 23). Plaintiff specifically alleges that he "read and relied on the words 'Once Daily Relief,' 'Full 24 Hour,' and '30 Day Supply' to expect if it were used once daily with one drop per eye, it would last thirty days." (*Id*. ¶ 25). Plaintiff claims he "paid more for the Product than he would have had he known the representations were false and misleading, as he would not have bought it or paid less." (*Id*. ¶ 27).

STANDARD OF REVIEW

I. Federal Rule of Civil Procedure 12(b)(1)

"Federal courts are courts of limited jurisdiction, and Rule 12(b)(1) requires dismissal of an action 'when the district court lacks the statutory or constitutional power to adjudicate it.'" *Schwartz v. Hitrons Sols., Inc.*, 397 F. Supp. 3d 357, 364 (S.D.N.Y. 2019) (quoting *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000)).[2] "The party invoking the Court's jurisdiction bears the burden of establishing jurisdiction exists." *Hettler v. Entergy Enters., Inc.*, 15 F. Supp. 3d 447, 450 (S.D.N.Y. 2014) (citing *Conyers v. Rossides*, 558 F.3d 137, 143 (2d Cir. 2009)). When deciding a motion to dismiss under Rule 12(b)(1) at the pleadings stage, "the Court 'must accept as true all material facts alleged in the complaint and draw all reasonable inferences in the plaintiff's favor.'" *Id*. (quoting *Conyers*, 558 F.3d at 143); *see also Doe v. Trump Corp.*, 385 F. Supp. 3d 265, 274 (S.D.N.Y. 2019). "Where, as here, the defendant moves for dismissal under Rule 12(b)(1), as well as on other grounds, the court should consider the Rule 12(b)(1) challenge

[2] Unless otherwise indicated, case quotations omit all internal citations, quotation marks, footnotes, and alterations.

first since if it must dismiss the complaint for lack of subject matter jurisdiction, the accompanying defenses and objections become moot and do not need to be determined." *Saint-Amour v. Richmond Org., Inc.*, 388 F. Supp. 3d 277, 286 (S.D.N.Y. 2019) (quoting *United States v. New York City Dep't of Hous., Pres. & Dev.*, No. 09-CV-06547, 2012 WL 4017338, at *3 (S.D.N.Y. Sept. 10, 2012)).

II. Federal Rule of Civil Procedure 12(b)(6)

On a Rule 12(b)(6) motion, a court may dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face "when the ple[d] factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant acted unlawfully." *Id*. The factual allegations pled "must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

"When there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679. Thus, the court must "take all well-ple[d] factual allegations as true, and all reasonable inferences are drawn and viewed in a light most favorable to the plaintiff[]." *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996). The presumption of truth, however, "'is inapplicable to legal conclusions,' and '[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.'" *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009) (quoting *Iqbal*, 556

U.S. at 678 (alteration in original)). Therefore, a plaintiff must provide "more than labels and conclusions" to show entitlement to relief. *Twombly*, 550 U.S. at 555.

III. Documents Considered

The Court, in deciding a Rule 12(b)(1) motion, "may refer to evidence outside the pleadings." *Makarova*, 201 F.3d at 113. Indeed, on such a motion, the Court "may consider affidavits and other materials beyond the pleadings to resolve the jurisdictional issue," along with "matters of which judicial notice may be taken." *Malloy v. Pompeo*, No. 18-CV-04756, 2020 WL 5603793, at *8 (S.D.N.Y. Sept. 18, 2020) (internal quotation marks omitted). On a Rule 12(b)(6) motion, "the Court is entitled to consider facts alleged in the complaint and documents attached to it or incorporated in it by reference, documents 'integral' to the complaint and relied upon in it, and facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence." *Heckman v. Town of Hempstead*, 568 F. App'x 41, 43 (2d Cir. 2014).

Defendant asks the Court to take judicial notice of the following extraneous documents proffered on this motion which are publicly available on the FDA website: (i) the Pataday® Once Daily Relief Extra Strength New Drug Application Approval Letter, dated February 14, 2020 ("Approval Letter"); and (ii) the Final Printed Label for the Pataday® Once Daily Relief Extra Strength product (the "FPL"). (*See* Doc. 20-1 ("Di Domenico Decl.") Exs. B-C). Defendant explains in its opening brief that the Approval Letter was issued by the United States Food and Drug Administration ("FDA") on April 15, 2019 in connection with the FDA's approval of Defendant's Supplemental New Drug Application for the Product, and that the FPL was submitted thereafter. (Def. Br. at 10). Defendant's request to take judicial notice is unopposed.

"Rule 201 of the Federal Rules of Evidence permits judicial notice of a fact that is 'either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate

and ready determination by resort to sources whose accuracy cannot be reasonably[ ] questioned.'" *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 411 (S.D.N.Y. 2011) (quoting *U.S. v. Bryant*, 402 Fed.Appx. 543, 545 (2d Cir.2010)). "[I]t is well-established that courts may take judicial notice of publicly available documents on a motion to dismiss." *Porrazzo*, 822 F. Supp. 2d at 411. Here, given that the Approval Letter and FPL are publicly available on the FDA website and Plaintiff does not challenge their authenticity or accuracy, the Court will take judicial notice of these documents for "the fact that the statements were made, not for their truth." *Id*. at 412; *see Gordon*, 2022 WL 836773 at *2 (taking judicial notice of FDA guidance documents and noting that "courts routinely take judicial notice" of such documents); *see also Becker v. Cephalon, Inc.*, No. 14-CV-03864, 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015) (taking judicial notice of FDA letters "publicly available on the FDA website.").

ANALYSIS

I. Federal Rule of Civil Procedure 12(b)(1): Standing

The Court must first address whether Plaintiff has standing to bring the claims asserted in his First Amended Complaint before determining whether they are stated plausibly. *See Buonasera v. Honest Co.*, 208 F. Supp. 3d 555, 560 (S.D.N.Y. 2016). The Supreme Court has held that parties pressing claims in federal courts must have standing to bring their claims to ensure that there is an actual case or controversy under Article III. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). A plaintiff has standing if she has suffered "(1) an injury that is (2) 'fairly traceable to a defendant's allegedly unlawful conduct' and that is (3) 'likely to be redressed by the requested relief.'" *Id.* 560-61 (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)). For the purposes of standing, an injury must be an injury in fact, meaning "an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not 'conjectural' or 'hypothetical.'" *Id.* at 560 (citations omitted). A plaintiff's pleading must only allege, to survive a

motion to dismiss, facts that "affirmatively and plausibly suggest" his standing to sue. *Lowell v. Lyft, Inc.*, 352 F. Supp. 3d 248, 255 (S.D.N.Y. 2018) (citing *Boelter v. Hearst Commc'n, Inc.*, 192 F. Supp. 3d 427, 437 (S.D.N.Y. 2016)).

Plaintiff alleges that he bought and utilized the Product over the course of several months, including months where he did not receive any replacement bottles. (AC ¶ 6). Defendant argues that Plaintiff's admission that he continued using the Product after learning that it did not last him the 30 days "precludes his assertion of any injury traceable to Alcon's allegedly misleading labeling and thus forecloses standing." (Reply at 10). Plaintiff responds that he has standing based on his price premium theory of injury under GBL § 349. (Pl. Br. at 9). Plaintiff's price premium theory of injury, which was also argued by the parties in connection with the GBL claims, is addressed *infra*. With respect to Defendant's argument, the Court declines to find that any such admission regarding continued use forecloses standing here. Plaintiff alleges that he "[initially] thought that he may have purchased irregular batches with less than the amount indicated," contacted Defendant, and received three replacement bottles. (AC ¶¶ 4-6). These allegations do not equate to Plaintiff having "full knowledge that . . . [the Product] allegedly did not last 30 days" and continued to use the Product. (Reply at 10). Therefore, Defendant's motion to dismiss is denied on the basis of standing.

II. Federal Rule of Civil Procedure 12(b)(6): Failure to State a Claim for Relief

A. First Claim for Relief: New York General Business Law §§ 349 and 350

Plaintiff's first claim for relief alleges violations of both GBL §§ 349 and 350. "Section 349 'prohibits deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.'" *Shakespeare v. Compu-Link Corp.*, 848 F. App'x 474, 476 (2d Cir. 2021) (quoting *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015)). Section 350 "prohibits false advertising in the conduct of any business, trade or commerce or in the furnishing

of any service in this state." *Orlander*, 802 F.3d at 300 (cleaned up). "'The standard for recovery under . . . § 350, while specific to false advertising, is otherwise identical to 349,' and therefore the Court will merge its analysis of the two claims." *Cosgrove v. Oregon Chai, Inc.*, 520 F. Supp. 3d 562 (S.D.N.Y. 2021) (quoting *Goshen v. Mut. Life Ins. Co. of N.Y.*, 774 N.E.2d 1190 (N.Y. 2002)); *see also Housey v. Proctor & Gamble Co.*, No. 22-888, 2022 WL 17844403, at *1 (2d Cir. Dec. 22, 2022) ("Section 350 of the GBL prohibits false advertising in the conduct of any business, trade or commerce, and is analyzed under the same reasonable consumer standard as Section 349").

"To successfully assert a claim under either section, 'a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice.'" *Orlander*, 802 F.3d at 300 (quoting *Koch v. Acker, Merrall & Condit Co.*, 967 N.E.2d 675 (N.Y. 2012)). Defendant raises two arguments relevant to Plaintiff's GBL claims: (i) New York's safe harbor law precludes Plaintiff's GBL claims; and (ii) Plaintiff has not suffered an injury. (Def. Br. at 17-31).

A. Safe Harbor

Defendant argues that because Plaintiff "does not allege that Defendant failed to comply with FDA regulations as the FDA interprets them," Plaintiff's GBL claims are barred by New York's safe harbor provision. (Def. Br. at 20). Section 349(d) provides:

> In any such action it shall be a complete defense that the act or practice is, or if in interstate commerce would be, subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission or any official department, division, commission or agency of the United States as such rules, regulations or statutes are interpreted by the federal trade commission or such department, division, commission or agency or the federal courts.

N.Y. Gen. Bus. Law § 349(d).

Here, the Court declines to find that the safe harbor provision applies based on the absence of an allegation regarding Defendant's non-compliance with FDA regulation. The Court cannot determine based on the allegations in the First Amended Complaint and the documents of which it has taken judicial notice that the Product's labeling complies with federal law. (Reply at 12). Accordingly, the Court finds that Defendant has not established as a matter of fact and law an affirmative defense under New York's safe harbor provision. *Bardsley v. Nonni's Foods LLC*, No. 20-CV-02979, 2022 WL 814034, at *12 (S.D.N.Y. Mar. 16, 2022) ("Defendant fails to carry its burden in asserting an affirmative defense under the safe harbor provisions because Defendant does not point to any facts appearing on the face of the Amended Complaint that support its affirmative defense: that the Product's packaging complied with the federal requirements under the FDCA and its implementing regulations.").

B. Injury

Defendant argues that Plaintiff fails to allege a cognizable injury under the GBL. (Def. Br. at 20). Plaintiff contends that he adequately alleged an injury based on a price premium theory. (Pl. Br. at 8-9). To plead an injury pursuant to either GBL §§ 349 or 350, "a plaintiff must allege that, on account of a materially misleading practice, [he] purchased a product and did not receive the full value of [his] purchase." *Orlander*, 802 F.3d at 302. "In the consumer goods context, an allegation of a defendant's deception alone does not suffice to plead injury, because a plaintiff may have received the benefit of the bargain despite the alleged misrepresentation." *Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 576 (S.D.N.Y. 2021). Instead, a plaintiff "must plead something more than the defendant's deception; for example, that the price of the product was inflated as a result of defendant's deception or that use of the product adversely affected plaintiff's health." *Preira v. Bancorp Bank*, 885 F. Supp. 2d 672, 676-77 (S.D.N.Y. 2012) (cleaned up).

An injury under §§ 349 and 350 therefore may be alleged under a price premium theory whereby a plaintiff claims to have paid more for the product than he or she would have paid if the defendant did not engage in allegedly deceptive practices. *See e.g., Orlander*, 802 F.3d at 302; *Duran v. Henkel of Am., Inc.*, 450 F. Supp. 3d 337, 350-51 (S.D.N.Y. 2020). A price premium theory requires a plaintiff to "allege that a company marketed a product as having a unique quality, that the marketing allowed the company to charge a price premium for the product, and that the plaintiff paid the premium and later learned that the product did not, in fact, have the marketed quality." *Duran*, 450 F. Supp. 3d at 350 (cleaned up).

Plaintiff alleges that "the Product is sold at a premium price, approximately no less than $12.99 for 2.5 mL (0.085 fl oz), excluding tax and sales, higher than similar products, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions." (AC ¶ 9). Plaintiff further alleges that he "relied on the words 'Once Daily Relief,' 'Full 24 Hour,' and '30 Day Supply' to expect if [the Product] were used once daily with one drop per eye, it would last thirty days," and that he "would not have bought [the Product] or paid less" had he known the representations were false and misleading." (*Id*. ¶¶ 25-27). These allegations sufficiently allege a price premium theory at this stage. All that is required to allege injury under GBL §§ 349 and 350 is that the Plaintiff "disclose sufficient information to permit the defendant to have a fair understanding of what the plaintiff is complaining about and to know whether there is a legal basis for recovery." *Harnage v. Lightner*, 916 F.3d 138, 141 (2d Cir. 2019) (quoting *Kittay v. Kornstein*, 230 F.3d 531, 541 (2d Cir. 2000)). Here, Plaintiff specifically alleges that Defendant labels the Product as a "30 Day Supply," and that he "did not expect the Product would last about twenty days, one-third fewer days than promised." (AC ¶¶ 25-27).

Accordingly, Plaintiff has sufficiently pled an injury in connection with his claims alleging violations of GBL §§ 349 and 350.

C. Affirmative Defense of Preemption

Defendant also asserts the affirmative defense of preemption. Preemption is a creature of the Supremacy Clause of the United States Constitution which states that "the Laws of the United States . . . shall be the supreme Law of the Land . . . ." U.S. Const. art. VI, cl. 2; *see also Fawemimo v. Am. Airlines, Inc.*, 751 F. App'x 16, 18 (2d Cir. 2018) (explaining that the Supremacy Clause "invalidates state laws that interfere with, or are contrary to, federal law" (quoting *Air Transp. Ass'n of Am., Inc. v. Cuomo*, 520 F.3d 218, 220 (2d Cir. 2008)). Although preemption is an affirmative defense to be pled and proven, it "can still support a motion to dismiss if the . . . barrier to suit is evident from the face of the complaint." *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 236 n.3 (2d Cir. 2021) (quoting *Ricci v. Teamsters Union Loc. 456*, 781 F.3d 25, 28 (2d Cir. 2015)). Where, as here, preemption is considered on a motion to dismiss, "[a] district court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted." *Reid v. GMC Skin Care USA Inc.*, No. 15-CV-00277, 2016 WL 403497, at *8 (N.D.N.Y. Jan. 15, 2016) (quoting *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 444 (2d Cir. 2015)).

As reiterated by the Second Circuit, generally:

> three types of preemption exist: (1) express preemption, where Congress has expressly preempted local law; (2) field preemption, where Congress has legislated so comprehensively that federal law occupies an entire field of regulation and leaves no room for state law; and (3) conflict preemption, where local law conflicts with federal law such that it is impossible for a party to comply with both or the local law is an obstacle to the achievement of federal objectives.

Williams v. Marinelli, 987 F.3d 188, 198 (2d Cir. 2021) (internal quotation marks omitted). Defendant argues that the Federal Food, Drug, and Cosmetic Act ("FDCA") both expressly and impliedly preempts Plaintiff's claims. (Def. Br. at 11-21).

i. Express Preemption

Express preemption exists where the "intent to preempt state law is explicitly stated in the statute's language." *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 530 (S.D.N.Y. 2008) (internal quotation marks omitted). The FDCA provides that absent certain exceptions:

> [N]o State or political subdivision of a State may establish or continue in effect any requirement--
>
> (1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and
>
> (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

21 U.S.C. § 379r(a); *see also Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 319 (S.D.N.Y. 2017) (concluding, *inter alia*, that 21 U.S.C. § 379r "preempt[s] state law labeling or packaging requirements that are not identical to FDA requirements"); *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 374-75 (S.D.N.Y. 2014) ("Under section 379r of the FDCA, state law claims that depart in any way from FDA regulation . . . are expressly preempted."); *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35 (2d Cir. 2020). Accordingly, the parties agree that federal law expressly preempts any state law governing OTC drugs that that would impose a requirement "different from," "in addition to," or "otherwise not identical" with federal labeling requirements. (Reply at 22; Opp. at 11). *See also Singo v. Ricola USA, Inc.*, No. 22-CV-10369, 2024 WL 196709, at *4 (S.D.N.Y. Jan. 18, 2024) ("Section 379r(a) thus preempts any state requirement that 'is different from or in addition to' or 'that is otherwise not identical with' the FDCA.").

Defendant's preemption argument rests on the premise that that the Product originally entered the market through the NDA approval process (as opposed to the OTC pathway) and, after

receiving approval, the FDA required that the Product's final printed label be "identical" to the FDA-approved version of the label—which included the "30 Day Supply" language. (Def. Br. at 12-15). Therefore, according to Defendant, the "federal requirement that the Product's label be identical to the label approved by the FDA expressly preempts Plaintiff's claims against Alcon" because Plaintiff's state law claims would require "removal of FDA-approved and . . . ***FDA-mandated*** language in the Product's label." (Def. Br. at 21; Reply at 10 (emphasis in original)). Plaintiff counters that he is not seeking to impose requirements different from or in addition to the FDCA because the relevant federal regulations "contain no reference to how long the Product will last." (Pl. Br. at 10-12).

As a threshold matter, Defendant's purported requirement that the FPL be "identical" to the FDA-approved label cannot be found within the four corners of the First Amended Complaint. Defendant cites to the Approval Letter as the basis for this requirement. (Def. Br. at 12-15, 21). But the Court may take judicial notice of the Approval Letter only for "the fact that the statements were made, not for their truth." *See Porrazzo*, 822 F. Supp. 2d at 411; *see also Gordon*, 2022 WL 836773 at *2 (taking judicial notice of FDA guidance documents "'for the limited purpose of determining what statements it contains' . . . 'not for the truth of the matters' . . . as alleged by Defendant."); *Casey v. Odwalla, Inc.*, 338 F. Supp. 3d 284, 295 (S.D.N.Y. 2018) ("[I]f [FDA letters are] judicially noticeable, this Court would be unable to consider the facts for the truth of the matter asserted."). The Court cannot, relying solely on the Approval Letter, accept as true that the FDA required (and continues to require) Defendant to use a final printed label that is identical

to the FDA-approved label.[3] It follows that the Court cannot consider the "30 Day Supply" statement as "FDA-mandated language." [4]

Moreover, Defendant argues that the FDA has exclusive authority to decide what is misbranded. (Def. Br. at 15). The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). A drug is misbranded under the FDCA when "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1). However, Plaintiff's challenge to the truthfulness of the "30 Day Supply" statement may not be a basis for preemption. *Leboeuf v. Edgewell Pers. Care Co.*, No. 22-CV-00642, 2023 WL 5432265, at *9 (N.D.N.Y. Aug. 23, 2023) ("Plaintiff merely seeks to impose requirements identical to the FDCA provisions prohibiting false or misleading product labeling . . . Such claims are not preempted."); *see also Simeone v. T. Marzetti Co.*, No. 21-CV-09111, 2023 WL 2665444, at *8 (S.D.N.Y. Mar. 28, 2023) ("Plaintiffs' claims are not preempted by the FDCA because they do not address the sufficiency of Defendant's labelling under the FDCA but rather its truthfulness."). Accordingly, Defendant's affirmative defense of express preemption fails at this juncture.

ii. Implied Preemption

"Conflict preemption, a form of implied preemption, refers to situations where compliance with both state and federal law is a physical impossibility, or . . . where the state law at issue 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Marentette v. Abbott Lab'ys, Inc.*, 886 F.3d 112, 117 (2d Cir. 2018) (quoting *Arizona*,

[3] Of Course, if properly submitted, a letter from the FDA "can be considered and given preemptive effect on a motion for summary judgment." *Casey*, 338 F. Supp. 3d at 295 (S.D.N.Y. 2018).

[4] Defendant's express preemption argument, which is based on deviation from a labeling requirement imposed by the Approval Letter, is different than *Singo* where the Court construed plaintiff as seeking deviation from the clearly applicable labeling requirements imposed by the FDCA. 2024 WL 196709 at *5.

567 U.S. at 399). Here, Defendant asserts conflict preemption based on impossibility. (Def. Br. at 16). "The proper question for impossibility analysis is whether the private party could independently do under federal law what state law requires of it." *Frei v. Taro Pharms. U.S.A., Inc.*, 443 F. Supp. 3d 456, 466 (S.D.N.Y. 2020), *aff'd sub nom.*, 844 F. App'x 444 (2d Cir. 2021) (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011)). "Impossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

Defendant argues that it "would be impossible for Alcon to simultaneously comply with both its federal requirement to label the Product with labeling 'identical' to the FDA's approved label (which says '30 Day Supply') and Plaintiff's asserted state-law obligation not to label the Product with '30 Day Supply'. . . ." (Def. Br. at 16). However, as discussed *infra*, the Court cannot at this stage accept as true that Defendant is subject to a federal requirement concerning "identical" labeling.

Defendant also argues that it is unable to unilaterally alter its label without prior FDA approval. (Def. Br. at 17). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *PLIVA, Inc.*, 564 U.S. at 623-24. Defendant specifically argues that, as an NDA holder, it cannot change the Product's label to remove the words "30 Day Supply" without prior FDA approval. (Def. Br. at 16-17). Plaintiff counters that the relevant regulations "contain no reference to how long the Product will last" and, therefore, Defendant would still be able to alter the "30 Day Supply" statement without first obtaining federal regulatory approval. (Pl. Br. at 11). The statute relied on by Defendant—21 CFR 314.70(b)(2)(v)—which defines major labeling changes that require supplemental submission and approval by the FDA, does not specifically reference

"supply" information and carves out certain exceptions that may be applicable here. At this stage, the Court cannot determine based upon movant's motion papers whether a change to the "30 Day Supply" statement constitutes a "major change" that requires FDA approval. Therefore, Defendant fails to establish implied preemption.

Based upon the foregoing, the Court simply cannot reach the conclusion at this juncture that Plaintiff's claims are preempted and thus subject to dismissal. Defendant's motion to dismiss on the basis of preemption is, accordingly, denied. [5]

III. Second Claim for Relief: Breach of Express Warranty

Defendant argues that Plaintiff fails to identify an express warranty that would be misleading to a reasonable consumer. (Def. Br. at 20-21; Reply at 13). "Express warranties are created as follows:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description."

Richardson v. Edgewell Pers. Care, LLC, No. 23-128, 2023 WL 7130940, at *2 (2d Cir. Oct. 30, 2023) (citing N.Y. U.C.C. § 2-313(1)(a)-(b)). "New York breach of express warranty claims require (i) a material statement amounting to a warranty; (ii) the buyer's reliance on this warranty as a basis for the contract with his immediate seller; (iii) the breach of this warranty; and (iv) injury to the buyer caused by the breach." *Lugones v. Pete & Gerry's Organic, LLC*, 440 F. Supp. 3d 226, 244 (S.D.N.Y. 2020) (cleaned up). Defendant contends that the "30 Day Supply" statement

[5] It is possible that the challenged representation is preempted by specific provisions of the FDCA or related regulations. Accordingly, although the Court is unable to conclude on the extant motion that the claims are preempted, that determination does not foreclose revisiting the issue at summary judgment and after the close of discovery.

was an "affirmation of fact" that the Product would yield a thirty-day supply. (Pl. Br. at 13). The Court agrees. A reasonable consumer could plausibly interpret the "30 Day Supply" statement as a promise by Defendant that the Product, when used as directed, will last for thirty days. Accordingly, Defendant's motion to dismiss Plaintiff's claim for relief for breach of express warranty is denied.

CONCLUSION

For the foregoing reasons, the Court DENIES Defendant's motion to dismiss Plaintiff's First Amended Complaint. Defendant is directed to file an Answer to the First Amended Complaint within 14 days of the issuance of this Opinion and Order.

The Clerk of the Court is respectfully directed to terminate the motion sequence pending at Doc. 20.

SO ORDERED:

Dated: White Plains, New York
February 14, 2024

Hon. Philip M. Halpern
United States District Judge